SANOFI

4th December 2019

Direct Healthcare Professional Communication

Insuman (recombinant human insulin): permanent discontinuation of 3 presentations – end of supply in 2020

Dear Healthcare Professional,

In agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), Sanofi would like to inform you of the discontinuation of 3 Insuman presentations (recombinant human insulin). The Department of Health and Social Care (DHSC) has been informed.

Summary

- 3 presentations of Insuman recombinant human insulin are to be discontinued due to limited capacity at the manufacturing site. This is **not due to any safety issue,** and Insuman currently on the market can continue to be used

- No new patients should be started on the below presentations

- Switching of insulins should be done under the supervision of a healthcare professional who can provide training on how to use the new delivery device (pen); blood glucose levels should be closely monitored while the patient becomes familiar with their new product

- Presentations to be discontinued (and suggested alternatives) are:
  Insuman Cartridges
  1. **Insuman Comb 15** 100 IU/mL- suspension for injection in a cartridge - Subcutaneous use.
     Expected End of Supply – June 2020 (there are approximately 300 patients in the UK)
     There is no alternative Insuman Comb 15 presentation available

  Insuman Vials
  2. **Insuman® Basal** 100 IU/mL- suspension for injection in a vial - Subcutaneous use.
     Expected End of Supply – May 2020 - (there are approximately 50 patients in the UK)
     Alternative Insuman Basal Presentation - Cartridge and Prefilled SoloStar Pen

  3. **Insuman® Comb 25** 100 IU/mL- suspension for injection in a vial - Subcutaneous use.
     Expected End of Supply – June 2020 (there are approximately 250 patients in the UK)
     Alternative Insuman Comb 25 Presentation - Cartridge and Prefilled SoloStar Pen

What are the implications for patients?

In case of a withdrawal, patients previously treated with Insuman vials and cartridges should preferably be switched to an alternative suitable human insulin preparation. This should be done under the supervision of a healthcare professional who will provide training on how to use the new delivery device (pen) which is specific to the alternative product. While patients become familiar with the delivery device their blood glucose levels should be closely monitored.

Interruption of insulin treatment is potentially life threatening. Therefore replacement with alternative insulin formulations is needed to avoid hyperglycaemia and serious complications. **It is therefore recommended that no new patients should be started on the products to be discontinued**

Switching to an alternative human insulin

Insuman ®	Alternative Human Insulin
Basal Vial	**Insuman Basal Cartridge** **Insuman Basal SoloStar** **Humulin® I Vial**
Comb 25 Vial	**Insuman Comb 25 Cartridge** **Insuman Comb 25 SoloStar** **Humulin® M3 Vial**
Comb 15 Cartridge	**Insuman Comb 25 Cartridge** **Humulin® M3 Cartridge**

Switching from Insuman Basal to another basal human insulin may require minimal or no dose adjustment.

Switching from Insuman Comb 15 to the alternative insulins will require close medical supervision. The differences in proportions of the soluble and isophane insulins are likely to be clinically significant and a dose adjustment would be anticipated.
Insuman Comb 15 has a ratio of 15% dissolved insulin and 85% crystalline protamine insulin
Insuman Comb 25 has a ratio of 25% dissolved insulin and 75% crystalline protamine insulin
Humulin M3 has a ratio of 30 % soluble insulin / 70 % isophane insulin.

Any switch to insulin analogues should be done under careful medical supervision as the pharmacokinetic and pharmacodynamic profiles of insulin analogues are different from human insulins, as are the international units used for human insulins and the analogue-specific units. As a result, switching patients from Insuman to an insulin analogue may require adjustments in the dose and/or dosing regimen on a case by case basis.

Please note that a statement on Insuman discontinuation is also being sent to diabetes patients' organisations.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.
Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number. Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card Scheme.

This information may also be reported to the **Sanofi UK Pharmacovigilance** department at:

- Sanofi, 410 Thames Valley Park Drive, Reading, RG6 1PT, UK -Tel: 0800 0902314
- Email: uk-drugsafety@sanofi.com

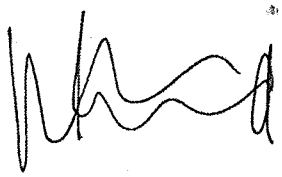
Company contact point

Should you have any question or require additional information, please contact:
Medical Information at Sanofi, 410 Thames Valley Park Drive, Reading, RG6 1PT, UK

- Tel: 0845 372 7101,
- Email: uk-medicalinformation@sanofi.com.

For questions relating to order of product:
Sanofi Customer Services – 0800 854 430, (9am – 5 pm Monday-Thursday, 9am – 4pm Friday).

Yours faithfully,



Dr Hubert Bland
Medical Director, UK and Ireland

Date of Preparation : November 2019